

DoD POLICIES ON FORCE HEALTH PROTECTION: MEDICAL DEFENSE AGAINST BIOLOGICAL WARFARE AGENTS (DoD DIRECTIVES, DoD INSTRUCTIONS)

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Opinions, interpretations, conclusions, and recommendations are those of the author and are not necessarily endorsed by the U.S. Army.

INTRODUCTION

The concept of force health protection (FHP) defines the medical defense approaches to maintain the health of the men and women who serve in the U.S. Armed Forces, to minimize or eliminate casualties, and to provide superior casualty care. Medical defense against biological warfare (BW) agents, whether encountered on a battlefield or as a result of bioterrorism, forms an important part of this strategy. Summarized here are directives, instructions, and other policy statements published by the U.S. Department of Defense (DoD) that apply to the medical aspects of FHP against BW threats (Tables 1 and 2). These statements focus on medical countermeasures, medical surveillance, health risk assessment, and preparedness training.

DOD ISSUANCES FOR FHP AGAINST BW AGENTS

Medical policies in the U.S. military to prevent disease can be traced back to 1777, when General George Washington ordered that his troops be variolated (the method of conferring active immunity that was employed prior to the advent of vaccination) against smallpox. More than 200 years later, this disease is again a focal point of FHP efforts, as policies and instructions were given in 2002 to begin vaccinating military personnel against this potential BW threat. This section will review some of the more recent DoD medical policy statements and some of the federal laws mentioned within these issuances that deal with these health threats.

The DoD defines BW agents as microorganisms or biologically derived poisons (i.e., toxins) that are developed

into weapons and intentionally used to cause human disease or fatalities (DoD Directive 6205. 3, 1993). Driven by the health concerns after Operation Desert Storm in 1991, new health care policies and plans are continuously being developed and implemented to enhance the protection of U.S. military personnel against diseases and environmental hazards, including BW agents (Mazzuchi et al., 2002). In this effort, the DoD and other agencies were directed by (Presidential Review Directive, National Science and Technology Council-5 (PRD/NSTC-5), 1998) to review their existing policies and develop plans to help establish new FHP programs. Recommendations were made to alter policies and doctrines concerning threat analyses, medical countermeasures (vaccines and therapeutic drugs), medical surveillance (record keeping, detection, and epidemiology), health risk assessments (occupational and environmental), and preparedness training.

DoD policies can be promulgated as DoD directives (DoDDs) that establish or guide activity of the Army, Navy, Air Force, Marines, National Guard, Reserve components, and other DoD organizational units. These broad policy statements reflect the requirements set forth by legislation, the President, or the Secretary of Defense (SECDEF). Senior military and civilian DoD officials issue memoranda that can also become policy statements. Within these directives, missions are defined and responsibilities are assigned, while policies, programs, and organizations are established or described. Individuals affected by DoD's health care policies, in addition to military personnel, can include essential civilians in the DoD and other federal departments when assigned as part of the U.S. Armed Forces, as well as beneficiaries of the military health system (MHS).

General guidelines for implementing these policies, outlining procedures, and assigning more detailed responsibilities are found in DoD instructions. Detailed technical instructions can come in the form of memos from the

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Table 1. DoD Directives and Instructions Related to FHP Against BW Agents^a

DoDD/DoDI	Number ^b	Title	Publication Date	Web Address ^c
Directive	5136.1	Assistant Secretary of Defense for Health Affairs	December 2, 1992	http://www.dtic.mil/whs/directives/corres/html/51361.htm
Directive	5160.5	Responsibilities for Research, Development, and Acquisition of Chemical Weapons and Chemical and Biological Defense	May 1985	http://www.dtic.mil/whs/directives/corres/html/51605.htm
Directive	6025.3	Clinical Quality Management Program in the Military Health Services	July 20, 1995	
Directive	6200.2	Use of investigational new drugs for force health protection	August 1, 2000	http://www.dtic.mil/whs/directives/corres/html/62002.htm
Directive	6205.2	Immunization requirements	1989	http://usmilitary.about.com/library/milinfo/dodreg/bldodreg6205-2i.htm?terms=6205.2
Directive	6205.3	DoD immunization program for biological weapons defense	1993	http://www.dtic.mil/whs/directives/corres/html/62053.htm
Directive	6490.2	Joint Medical Surveillance	August 30, 1997	http://www.dtic.mil/whs/directives/corres/html/64902.htm
Instruction	1322.24	Military Medical Readiness Skill Training	December 20, 1995	http://www.dtic.mil/whs/directives/corres/html/132224.htm
Instruction	6490.3	Implementation and Application of Joint Medical Surveillance for Deployments	August 7, 1997	http://www.dtic.mil/whs/directives/corres/ins1.html

^aTables 1 and 2 were modified from (Mazzuchi et al., 2002).

^bDoDD and DoDI numbered series of categories relevant to BW defense.

2000—International and Foreign Affairs.

3000—Plans and Operations, Research and Development, Intelligence, and Computer Language.

5000—Acquisition and Administrative Management, Organizational Charters, Security, and Public and Legislative Affairs.

6000—Health.

(from <http://www.fas.org/irp/doddir/dod/index.html>)

^cAll websites were accessible in March 2003.

senior leadership, such as the 2002 memo from the Assistant Secretary of Defense for Health Affairs (ASD(HA)) that established policy for reinstating the administration of smallpox vaccine. Most of these issuances are currently available on the worldwide web (see Tables 1 and 2 for more information).

As described in DoDD 5136.1 (1992), the ASD(HA) assists the SECDEF in DoD-related health policy issues and oversees the MHS, including all aspects concerning the delivery of health care services. The fundamental missions of the MHS are to support military readiness and peacetime health care, both of which include FHP (● Baily, 1999). FHP in turn involves three strategic programs: surveillance and casualty prevention programs designed to protect against endemic diseases and environmental hazards (including BW agents), and clinical programs that provide casualty care and management (Joint Publication 4-02, 2001).

Public Law 105-85 established the requirements of maintaining records of all health care services, including vaccinations, in a centralized location; conducting and recording pre- and postdeployment medical examinations; and recording changes in a service member's medical condition during deployment. FHP policy by the Joint Chiefs of Staff also takes into consideration host countries,

multinational forces, and civilians who provide essential support (Joint Publication 3–11, 2000).

Policymakers are supplied with feedback regarding FHP plans and their implementations from DoD-generated reports, analyses by other government agencies, and by nongovernment groups. Implementations of medical policy are summarized in congressionally mandated reports. For example, annual DoD reports on the Chemical and Biological Defense Program, in accordance with P.L. 103–160 Sec. 1523, are presented to Congress describing the overall organization of research and its progress toward protecting the health of military service members.

MEDICAL COUNTERMEASURES AGAINST BW AGENTS

The more recent DoD biodefense health policies began in 1976 with DoDD 5160.5, which assigned responsibility for chemical and biological defense research, development, testing, and evaluation. Revised in 1985 to update procedures for budgeting, programming, and operations, this directive also assigns responsibilities for DoD research, development, and the acquisition of countermeasures against chemical and biological agents. An example of a resulting implementation from DoDD 5160.5 is the Joint Medical Biological Defense Research Program. This program integrates DoD-supported internal and extramural

Table 2. DoD-issued Policy Statements Related to FHP Against BW Agents

DoD Issuances & Memoranda	Number	Title	Publication Date	Web Address ^a
ASD(HA) Memorandum	HA Policy 01–017	Updated policy for pre- and post-deployment health assessments and blood samples	October 25, 2001	http://chppm-www.apgea.army.mil/deployment/#DODandArmyPolicies
ASD(HA) Memorandum	None available	Clinical policy for the DoD smallpox vaccination program	November 26, 2002	http://www.smallpox.army.mil/resource/policies.asp
Joint Publication	3-11	Joint Doctrine for Operations in Nuclear, Biological, and Chemical Environments	July 11, 2000	http://www.dtic.mil/doctrine/jpoperations-seriespubs.htm
Joint Publication	4-02	Doctrine for Health Service Support in Joint Operations	July 30, 2001	http://www.dtic.mil/doctrine/jplogistics-seriespubs.htm
Joint Publication	5.00–2	Joint Task Force Planning Guidance and Procedures	April 13, 1999	http://www.dtic.mil/doctrine/jpplanning-seriespubs.htm
CJCS Memorandum	MCM-251-98	Deployment Health Surveillance and Readiness	December 4, 1998	Not currently available
CJCS Memorandum	MCM-0006-02	Updated Procedures for Deployment Health Surveillance and Readiness	February 1, 2002	http://www.dtic.mil/doctrine/other_directives.htm
Joint Instruction	AFJI 48-110; AR40-562; BUMEDINST 6230.15; CG COMDTINST M6230.4E	Immunizations and Chemoprophylaxis	November 1, 1995	http://afpubs.hq.af.mil/pubfiles
Army Regulation	525-13	Antiterrorism Force Protection: Security of Personnel, Information, and Critical Resources from Asymmetric Attacks	September 10, 1998	Not currently available
Army Medical Command Regulation	MEDCOM 525-4	Emergency Preparedness	December 11, 2000	http://chppm-www.apgea.army.mil/smallpox/

^aAll websites were accessible in March 2003.

basic research efforts leading to the development of vaccines, therapeutic drugs, and diagnostic tools to protect against and to deter the use of BW agents (Lebeda, 1997; DoD, 2002).

Vaccination policies for all members of the armed forces, civilian employees of the DoD, and eligible beneficiaries of the MHS are stated in DoDD 6205.2 (1989). Programs are outlined for diseases that can be prevented by vaccination. Specified civilian personnel, for example at risk DoD laboratory workers who may become exposed to pathogenic organisms, may also need to use vaccines other than those that are routinely administered.

The main DoD policies that are specific for vaccinating the armed forces against known or potential BW agents are summarized in DoDD 6205.3 (1993). The policies involve “research, development, testing, acquisition, and stockpiling” of vaccines to be used for biological defense. These vaccines are (or will be) either licensed or classified as Investigational New Drugs (INDs) by the Food and Drug Administration (FDA). DoDD 6200.2 (2000) provides further policy and guidance for the use of INDs for FHP. This document identifies at-risk armed forces personnel and DoD-related civilians who need to be protected from nuclear, biological, and chemical (NBC) threats and endemic diseases.

DoDD 6200.2 also incorporates the mandates of Title 10 USC 1107, Executive Order 13139 (1999), and the FDA interim final rule 21 CFR 50.23. The SECDEF, under 10.1107, must notify service personnel in writing that the specified drug they are to receive is an IND or a drug whose use, under the circumstances, is not approved by the FDA. Notification must also be given for the rationale for administering the drug, possible adverse reactions produced by the drug, and any other information required by the Secretary of the Department of Health and Human Services. Title 10 USC 1107 also allows the president to waive the prior consent requirement for administering INDs to service personnel. The policy in E.O. 13139 outlines procedures for informed consent requirements and waiver provisions. The FDA’s interim rule 21 CFR 50.23 permits the waiver of prior consent if personnel are already involved in a military operation in which exposures to NBC threats or other environmental hazards are imminent and likely to be lethal or cause serious illness. Just before Operation Desert Shield, this rule was invoked to allow the use of two INDs, pyridostigmine bromide and botulinum toxoid vaccine, to counter chemical and biological threats, respectively.

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The joint instruction published in 1995 for vaccinations and chemoprophylaxis outlines implementation requirements under the Armed Forces Immunizations Program for protecting individuals from endemic diseases and potential BW threats. Also provided are requirements for tracking vaccinations for an individual's health record. These vaccinations are intended for service personnel and selected civilians (federal employees and MHS-eligible family members).

SURVEILLANCE: RECORD KEEPING, DETECTION, AND EPIDEMIOLOGY

Medical (health) surveillance programs are designed to warn of and to reduce the incidence of illness. A memorandum by the Chairman of the Joint Chiefs of Staff (CJCS) (MCM-251-98, 1998) initially outlined a FHP plan that featured health surveillance as a key component. For joint operations, DoD Instruction (DoDI) 6490.3 (1997), by defining health surveillance requirements, implements policy, outlines procedures, and assigns responsibilities set forth in DoDI 6490.2 (1997). Medical surveillance is mandated for all members of the military services and reserve components before, during, and after military deployments. The main goals are to identify potential threats to health, which may include exposure to BW agents; to collect health data from multiple locations in the deployment area; and to communicate quickly the relevant data for storage, integration, and further assessment. The significant health risks are to be identified by the CJCS in coordination with the ASD(HA). In this Instruction, the Secretary of the Army is responsible for the operation and maintenance by the U.S. Army Center for Health Promotion and Preventive Medicine of a DoD Serum Repository that stores specimens for exclusive use in the diagnosis, prevention, and treatment of health problems associated with such deployments. Some of these FHP procedures are also referred to in joint doctrine (Joint Publication 5.00-2, 1999), while recent policies regarding health assessments before and after deployments are found in a memorandum by the ASD(HA) (HA Policy 01-017, 2001). The Defense Medical Surveillance System is responsible for maintaining these assessment data, which include both physical and psychological evaluations.

Instructions for assessing health readiness and conducting health surveillance in support of joint and unified command deployments were delivered in a memorandum from the CJCS (MCM-251-98, 1998). A more recent memorandum (MCM-0006-02, 2002) instructs that standardized health readiness assessments and health surveillances be conducted. This memo also places responsibility on the combatant command to decide which specific medical countermeasures, such as vaccines, antibiotics, or other drugs, are needed (Embrey, 2002). Epidemiology data are required to be analyzed and archived to report and track adverse reactions and illnesses that may occur after required vaccinations (DoDI 6205.2, 1986). Although each military service currently has its own vaccination-tracking program, the Preventive Health Care Application (PHCA) that is being developed will become the single

standard system to help deliver and track clinical preventive services.

OCCUPATIONAL AND ENVIRONMENTAL HEALTH RISK ASSESSMENTS

Relevant to BW agents, guidance for joint medical surveillance on nuclear, biological, or chemical battle or operational environments contaminated by other factors, such as toxic industrial chemicals, was provided in 1997 by DoDD 6490.2 and DoDI 6490.3. Both documents emphasize the need for accurate communication about potential environmental and health risks to service members. "Environmental risk assessments" predict the frequency of disease occurrence, based on environmental exposures, in a population, while predictions from "health hazard assessments" are based on occupational exposures. The CJCS memo (MCM-0006-002; 2002) outlines the process of occupational and environmental health (OEH) risk assessment in such environments. A part of this assessment is an Environmental Baseline Survey (EBS) at the site of deployment, which identifies occupational and environmental health and safety hazards and estimates their severity. Technical guidance in conducting this survey is in Field Manual FM 3-100.4 (2000). As part of the FHP program, the EBS documents these hazards. Commanders are instructed to use these surveillance measures to determine appropriate responses and communicate these risks with their forces. Commanders can then make informed choices and weigh mission requirements during operational planning against occupational and environmental health hazards.

MEDICAL TRAINING: PREPARING FOR A BW EVENT

The DoD has developed programs that provide and monitor military medical skills training in accordance with DoDI 1322.24 (1995). Knowledge of BW threats and medical consequence responses to BW exposure are provided by the U.S. Army Medical Department. Courses have been developed in the joint medical management of biological casualties. Three reference texts that accompany some of these courses are cited in the Further Reading and Web Resources section below. The U.S. Army Medical Command, in response to MEDCOM Regulation 525-4, is preparing a pamphlet on emergency preparedness that provides guidance on responses to emergencies including those involving the use of NBC weapons. Health-care providers within the military must also be certified when assigned to military operations (DoDD 6025.3, 1995). The certification process includes training in BW defense measures.

CONCLUSION

These directives, instructions, and other policy statements are designed to enhance FHP and the preparedness of the U.S. Armed Forces. It is expected that some of these health-related policies developed by the DoD after 1990 for military personnel will have civilian applications in

the post-September 11 era. It is also reasonable to expect that some of the implementations resulting from these DoD policies will help in the continuing struggle by the civilian public health sector to protect against current and emerging infectious diseases.

REFERENCES

Bailey, S., *Military Health System Overview Statement*, Submitted to the Personnel Subcommittee, Committee on Armed Services, US Senate, First Session, 106th Congress, March 11, 1999.

Code of Federal Regulations (21 CFR 50.23), Title 21 Food and Drugs, Part 50 Protection of Human Subjects, Subpart B Informed Consent of Human Subjects, Sec. 50.23 Exception from general requirements, Vol. 1, Revised as of April 1, 2002, pp. 288–290.

Code of Federal Regulations (21 CFR 312.21) Title 21 Food and Drugs, Part 312 Investigational New Drug Application, Sec. 312.21 Phases of an investigation, Vol. 5, pp. 61–62, Revised as of April 1, 2002.

Department of Defense, Chemical and Biological Defense Program, Vol. 1, Annual Report to Congress, April 2002.

Department of Defense, Chemical and Biological Defense Program, Annual Report to Congress and Performance Plan, July 2001.

Embrey, E., Deputy Assistant Secretary of Defense for Force Health Protection and Readiness, Department of Defense, Statement to the House Committee on Veterans Affairs Subcommittee on Health, February 27, 2002.

Lebeda, F.J., *Mil. Med.*, **162**, 156–161 (1997).

Mazzuchi, J.F., Trump, D.H., Riddle, J., Hyanms, K.C., and Balough, B., *Mil. Med.*, **167**, 179–185 (2002).

Presidential Review Directive, National Science and Technology Council-5, A National Obligation: Improving the Health of Our Military, Veterans, and Their Families, Executive Office of the President, Office of Science and Technology Policy, August 1998.

Public Law 103–160, National Defense Authorization Act for Fiscal Year 1994, Title 50 USC, Sec. 1522, Conduct of chemical and biological defense program, Sec. 1523, Annual report on chemical and biological warfare defense.

Public Law 104–201, National Defense Authorization Act for Fiscal Year 1997, Title XIV: Defense Against Weapons of Mass Destruction (WMD), Subtitle A: Domestic Preparedness, September 23, 1996.

Public Law 105–85, National Defense Authorization Act for Fiscal Year 1998.

Report 106–945, Conference Report to Accompany H.R. 4205, Enactment of Provisions of H.R. 5408, The Floyd D. Spence National Defense Authorization Act For Fiscal Year 2001.

FURTHER READING AND WEB RESOURCES

Eitzen, E., Pavlin, J., Cieslak, T., Christopher, G., and Culpepper, R., Eds., *Medical Management of Biological Casualties Handbook*, 4th ed., US Army Medical Research Institute of Infectious Diseases, Fort Detrick, MD, February 2001, <http://www.usamriid.army.mil/education/instruct.html>.

Franz, D., *Defense Against Toxin Weapons*, US Army Medical Research and Materiel Command, Fort Detrick, MD, 1997, <http://www.usamriid.army.mil/education/toxdefbook.doc>.

Headquarters Department of the Army, *Environmental Considerations In Military Operations*, (Field Manual 3–100.4, Marine Corps Reference Publication, MCRP4-11B), Headquarters United States Marine Corps, Washington, DC, June 15, 2000, <http://www.adtdl.army.mil/cgi-bin/atdl.dll/fm/3-100.4/toc.htm>.

Sidell, F.R., Takafuji, E.T., and Franz, D.R., “Medical Aspects of Chemical and Biological Warfare,” in R. Zajtchuk, Ed., *Textbook of Military Medicine*, Office of The Surgeon General, TMM Publications; Borden Institute, Walter Reed Army Medical Center, Washington, DC, 1997, <http://www.nbcm-med.org/SiteContent/HomePage/WhatsNew/MedAspects/contents.html>.

Treatment Of Biological Warfare Agent Casualties (Field Manual No. 8–284 NAVMED P-5042, Air Force Manual (Interservice) No. 44–156, Marine Corps MCRP 4–11.1C). Headquarters Departments of The Army, The Navy, and The Air Force and The Commandant, Marine Corps, Washington, DC, July 17, 2000 (incorporates Change 1, 8 July 2002), <http://www.adtdl.army.mil/cgi-bin/atdl.dll/fm/8-284/fm8-284.htm>.

See also DEPARTMENT OF DEFENSE; DETECTION OF BIOTERRORIST AGENTS; RISK ASSESSMENT IN BIOTERRORISM; and SYNDROMIC SURVEILLANCE.

• Q2

• Q3

• Q4

Queries in ebd054

- Q1. Please clarify if this name should be 'Baily' or 'Bailey.'
- Q2. 'Code of Federal Regulations (21 CFR 50.23), 2002', 'Code of Federal Regulations (21 CFR 312.21), 2002', 'DoD, 2001', 'Public Law 103-160, 2002', 'Public Law 104-201, 1996', 'Public Law 105-85, 1998' and 'Report 106-945, 2001' have not been cited in the text. Please provide the place of citation.
- Q3. Please provide the year of publication for this reference.
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